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Application No. 10/791,979 Amendment dated July 7, 2006 JUL u 7 2006 Attorney Docket No. CV06039US01

REMARKS

Applicants are pleased to note that claim 12 has been indicated as allowable if rewritten in independent form and sincerely appreciate the suggestions to facilitate allowance of the application.

Claims 1-33 are pending in this application. Claims 10, 11 and 27-28 have been withdrawn by the Examiner as being drawn to a non-elected invention. Claims 1, 4, 9, 12, 14, 16, 18, 26, 30 and 32 have been amended. The amendments to the abstract and claims 1, 4, 9, 12, 14, 16, 18, 26, 30 and 32 are supported in the specification, such as at page 23, line 5 through page 28, line 12. No new matter has been added to the application by any of the foregoing amendments.

Restriction Requirement and Provisional Election

A three-way restriction requirement was set forth at pages 2-3 of the Office Action. For brevity, these rejections are not repeated herein but reference is made to the Office Action.

Applicants respectfully traverse the restriction requirement and requests that the same be reconsidered and withdrawn.

At page 2 of the Office Action, it is alleged that sugars and peptides are structurally dissimilar to the other organic groups recited. Applicants assert that there is no undue burden to search the subject matter of each of the Groups (I - III) due to the main core of the molecule being similar to all of the groups of compounds. Therefore, reconsideration and withdrawal of the restriction requirement and election of species requirement is respectfully requested.

To facilitate prosecution of the application and in order to comply with the Examiner's requirements, Applicants hereby provisionally elect with traverse the claims of Group I (claims 1-9, 12-26 and 29-33) for initial examination in this application.

Rejections Under 35 USC § 112

At pages 3-5 of the Office Action, claims 1-9, 12, 14-26 and 29-33 have been rejected under 35 USC § 112, second paragraph, for alleged indefiniteness regarding:

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- (1) C₀ alkylene;
- (2) Substitution of groups such as alkyl;
- (3) $-N-N=N^+$;
- (4) Meaning of the term "diabetes";
- (5) Meaning of the term "sterol"; and
- (6) Meaning of the term "stanol".

Applicants respectfully traverse this rejection and request reconsideration and withdrawal thereof.

Regarding item (1) above, one skilled in the art would understand that $-(C_0-C_{10})$ alkylene)-G, for example, means that the alkylene moiety is not present when C is zero, i.e., there is a covalent bond between the main molecule and G, i.e., -G. If C is one, then the group would be $-CH_2G$, for example. While Applicants respectfully disagree with the rejection, to expedite examination of the application Applicants have amended claims 1 and 18 to delete reference to C_0 and instead show these moieties as, for example, -G.

Regarding item (2), while Applicants respectfully disagree with the rejection, to expedite examination Applicants have amended claims 1 and 18 to specify that each of the alkyl, alkenyl, alkynyl, alkylene, alkoxyalkoxy, alkoxyalkoxy, alkoxycarbonylalkoxy, alkoxyarylalkoxy, alkoxyiminoalkyl, alkyldioyl, allyloxy, aryl, arylalkyl, aryloxy, arylalkoxy, heteroaryl, benzoylbenzoyloxy, aroylaroyloxy, arylalkoxycarbonyl, aroyl, aroyloxy, heteroarylalkoxy, dioxolanyl, heterocyclyl, heterocyclylalkyl, heteroarylalkyl, heterocyclylcarbonyl, or heterocyclylcarbonylalkoxy groups, when present, is independently substituted or unsubstituted. This amendment is supported in the description of each moiety in the specification at page 23, line 5 through page 28, line 12.

Regarding item (3), Applicants have amended claims 1 and 18 to clarify that the azido moiety was intended.

Regarding item (4), the meaning of the term diabetes is intended to be inclusive and is well known to those skilled in the art. While Applicants respectfully disagree with the rejection, to expedite examination Applicants have amended claims 14, 16, 30 and 32 to specify diabetes mellitus, as discussed at page 1, line 18 of the specification.

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Regarding item (5), the term "sterol" is explained in the specification at page 47, lines 24-26 as including cholesterol and phytosterols, such as sitosterol, campesterol, stigmasterol and avenosterol and mixtures thereof. While Applicants respectfully disagree with the rejection, to expedite examination of the application claims 14, 16, 30 and 32 have been amended to cholesterol and phytosterols.

Regarding item (6), the term "stanol" is explained in the specification at page 47, lines 25-27 as including 5α -stanols, such as cholestanol, 5α -campestanol, and 5α -sitostanol and mixtures thereof. While Applicants respectfully disagree with the rejection, to expedite examination of the application claims 14, 16, 30 and 32 have been amended to 5α -stanols.

None of the foregoing amendments were made for any prior art reasons. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

At page 5 of the Office Action, claims 1-9, 14-26 and 29-33 have been rejected under 35 USC § 112, paragraphs 1 and 2, for lack of written description and lack of enablement for trialkylammonium alkyl radical. Applicants respectfully traverse and request reconsideration and withdrawal of this rejection. Applicants wish to point out that claim 1 includes pharmaceutically acceptable salts of the compound of Formula (I). Please see page 27, lines 3-13 for a discussion of suitable acids for salt formation and description of formation of the salts. In view of the claim language and disclosure in the specification, one skilled in the art can readily ascertain the meaning of salt of trialkylammonium alkyl. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

At pages 6-12 of the Office Action, claims 16 and 32 have been rejected under 35 USC § 112, first paragraph, for lack of written description or enablement as to the treatment of the disorders listed. Applicants respectfully traverse and request reconsideration and withdrawal of this rejection. While Applicants respectfully disagree with the rejection, to expedite examination of the application Applicants have amended claims 16 and 32 to specify vascular conditions, etc. without prejudice to the filing of one or more divisional applications directed to the amended subject matter. This amendment was not made for any prior art reasons. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

In view of the remarks above, reconsideration and withdrawal of the rejections, and favorable allowance of all claims is respectfully requested. Should the Examiner have any

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questions or wish to discuss this matter further, he is invited to contact Applicant's representative at 412-471-8815.

Respectfully submitted,

THE WEBB LAW FIRM

Date: July 7, 2006

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